EXHIBIT O

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March 29, 2013

Thomas P. Cartmell, Esquire
Wagstaff & Cartmell, LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112

Re: Ethicon/MDL Pelvic Mesh

Dear Tom:

On March 18, 2013, I sent you a letter regarding the Regulatory Affairs Central File copy of the TVT-O 510(k) submission (*see* attached). To summarize, you brought to our attention that the version we had produced to you was a copy that Ethicon had received from a FOIA response, rather than a copy of the original submission (i.e., a second generation copy). I promised to follow-up on this issue.

In the April 1, 2013, document production, a copy of the Regulatory Affairs Central File Copy of the TVT-O 510(k) submission will be produced. I do not believe it contains anything that was not included in the version that was previously produced but it does not bear the FOIA Bates stamp. The entire document is Bates stamped Eth.Mesh.07876926-Eth.Mesh.0787706. The 510(k) submission itself is Bates stamped Eth.Mesh.07876934-07876995. In addition to the submission, the larger document also contains: (a) FDA correspondence filed in the front of the binder (as explained by Susan Lin in her deposition); and (b) approximately 9 pages of FOIA obtained information related to the submission filed in the back of the binder. This is how the document is stored in place.

Additionally, in the April 1, 2013, document production, a copy of the Regulatory Affairs Central File Copy of the TVT-Secur 510(k) submission will also be produced. Previous copies of this had been produced but because part of it also contains a FOIA Bates stamp, I wanted to confirm that it is the copy as submitted. The entire document is Bates stamped Eth.Mesh.07876572-Eth.Mesh.07876819. The 510(k) submission itself is Bates stamped Eth.Mesh.07876581-07876699. In addition to the submission, the larger document also contains: (a) FDA correspondence related to the submission filed in the front of the binder; and (b) approximately 119 pages of FOIA obtained information related to the submission filed in the back of the binder. I note that there are pages omitted from the FOIA Bates ranges, this is not a

mistake in copying, this is how the document is stored in place. In other words, only a partial copy of the FOIA response has been filed in the binder.

In the April 1, 2013, document production, there is also a copy of the Regulatory Affairs Central File Copy of the FDA follow-up and supplementation related to the TVT-Secur 510(k) submission. Previous copies of this had been produced but, I wanted to confirm that it is the official file copy. The entire document is Bates stamped Eth.Mesh.07876820-Eth.Mesh.07876925. The 510(k) supplementation submission itself is Bates stamped Eth.Mesh.07876833-07876924. In addition to the supplemental submission, the larger document also contains correspondence to and from the FDA related to the submission filed in the front of the binder (as explained by Susan Lin in her deposition). Again, this is how the document is stored in place.

If you have any other questions, please contact me.

Very truly yours,

Philip J. Combs

PJC/blm

cc: Maha M. Kabbash, Esq.